

REMARKS

Upon entry of this amendment, claims 1-33 will be pending in the application, of which claims 1, 2, 6, 9, 12, 16, 18, 21, 22, 24, 25, 29 and 31 are being amended.

Claims 1 and 12 are being amended to recite moving the blades in a forward direction and across a distance through the cover to create at least one elongated opening in the cover. These amendments is supported by at least by original claims 2 and 6, and the Specification at page 9, lines 5-7, and page 13, lines 26-29.

The amendments to claims 2, 7, 16 and 18, are supported at least by the original claims and the Specification at page 9, lines 5-7, page 12, lines 14-16, and page 13, lines 26-29.

The amendments to claim 6 are supported at least by the Specification at page 11, 7-10.

The amendments to claim 21 are supported at least by the Specification at page 15, lines 1-3 and page 14 lines 31-32.

The amendments to claims 22, 24, 25, 29 and 31 are supported at least by original claims 2 and 6, and the Specification at page 9, lines 5-7, page 12, lines 14-16, and page 13, lines 26-29.

Thus the claim amendments are fully supported by the Specification and add no new matter. Entry of the claim amendments is respectfully requested.

Reconsideration of the present application, in view of the amendments and remarks made herein is respectfully requested.

Claim Rejections – 35 USC §103(a)

1. Claims 22-33 were rejected under 35 USC 103(a) as unpatentable over US patent no. 5,740,794 to Smith et al..

As amended, independent claims 22 and 23 and the claims dependent therefrom, are patentable under 35 U.S.C. 103(a) over Smith et al. because Smith et al. does not establish a *prima facie* case of obviousness over the amended claims. To establish a *prima facie* case of obviousness under 35 U.S.C. 103(a):

- (a) The claimed invention must be considered as a whole;
- (b) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (c) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (d) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Claim 22

Smith et al. does not teach amended claim 22, because Smith et al. does not teach a hole forming device to form an elongate opening in a cover of a receptacle, the device comprising a movable support member capable of being moved a distance through the cover in a forward direction; a plurality of outer blades extending in the same forward direction, and further extending downward from the support member at an angle in the range from about 50 degrees to about 80 degrees; and a tubular member extending downward from the support member, the member being surrounded by the outer blades, and the member having a distal end that includes a plurality of inwardly and outwardly facing blades.

As acknowledged by the Office Action, Smith et al., "does not provide plurality of blades extending downward from the support member at an angle in the range from about 50 to 80 degrees" as claimed in claim 22. However, in addition, Smith et al. does not teach a movable support member capable of being moved a distance through the cover in a forward direction, or a plurality of outer blades extending in the same forward direction, as claimed in claim 22.

Instead, in a section of Smith et al. cited by the Office Action, Smith et al. teaches a powder dispersing apparatus comprising a piercing mechanism 24 having a "...feed tube assembly 100 which permits direct penetration of a medicament receptacle lid" as shown in Figs. 10 and 11A and described in column 17, lines 3-36. Smith et al. further teaches:

As shown in detail in FIG. 11 [sic FIG. 11A], the penetrating element 140 includes a pair of crossing internal walls 142 which terminate in a pointed blade structure 144. The blade structure 144 leaves four separate flow passages 146 arranged in quadrants within the feed tube 104. The flow passages 146 may optionally stop beyond the attachment point of the blade structure 144 to the inside wall of the host tube.

Referring to Fig. 11A, it is seen that the element 140 having crossing internal walls 142 and pointed blade structure 144 are not the same as a movable support member capable of being moved a distance through the cover in a forward direction, and having a plurality of outer blades extending in the same forward direction and further extending downward from the support member at an angle in the range from about 50 degrees to about 80 degrees, as claimed in claim 22. The element 140 taught by Smith et al. is directed downward to achieve "direct penetration" and is moved a distance through the cover in a forward direction. Further, the crossing internal walls 142 and pointed blade structure 144 extend downward along the direction of the axis of the support element 140, and as such are blades that extend in a forward direction as claimed in claim 22.

In another version, as shown in Fig. 11B, Smith et al. teaches a penetrating structure 151 formed by machining a tube to form pointed elements which are pressed together to face each other across an opening 153. Smith et al. teaches:

FIG. 11B illustrates an alternative penetrating structure 151 formed by machining the end of a tube along two converging planes. The resulting pointed elements are then pressed together to form the structure having openings 153. The penetrating element 151 is advantageous since it peels back the lid as it is penetrated, leaving the openings 153 clear to receive powder. The penetrating structure 151 could be fabricated from molded plastic as well as machined metal. Again it is seen that the penetrating structure 151 comprises pointed elements which face each other, and as such are not blades that extend in the same forward direction as that along which the movable support can be moved, as claimed in claim 22.

In still another version shown in Fig. 7, which is also cited by the Office Action, Smith et al. does not teach a plurality of outer blades that extend in a forward direction along which the movable support can be moved, and downward from the support member at an angle in the range from about 50 degrees to about 80 degrees, as claimed in claim 22.

Smith et al. further teaches yet another version, shown in Fig. 1, in which a piercing mechanism 24 is "fixedly mounted" within the base, and accordingly, this structure is also not a movable support member capable of being moved a distance through the cover in a forward direction, as claimed in claim 22. Specifically, Smith et al. teaches:

In the embodiment of Fig. 1, penetrations will be formed in the lid of the strip of receptacles 12 by a piercing mechanism 24. As illustrated, the piercing mechanism 24 will be fixedly mounted within the base enclosure 11 and will include a plurality of sharpened penetrating elements 26 disposed to contact and penetrate the puncturable lid 92 (Fig. 3) of the receptacles 12 when the cartridge 22 is reciprocated, as illustrated in broken line in Fig. 1.

Smith et al., column 12, lines 60-67. In this version, the cartridge 22 is reciprocated, and the piercing mechanism 24 is fixed. Thus the piercing mechanism 24 is not a movable support member capable of being moved a distance through the cover in a forward direction, as claimed in claim 22. Further, the piercing mechanism 24 and plurality of sharpened penetrating elements 26, as seen in Fig. 1 of Smith et al., are pointed in a downward direction, and are thus not plurality of outer blades extending in a forward direction. Nor do the sharpened penetrating elements 26 extend downward from the support member at an angle in the range from about 50 degrees to about 80 degrees, as claimed in claim 22. Thus none of versions described in Smith et al. teach claim 22 as a whole.

Further, under the second part of the obviousness test, the combination of cited references, considered as a whole, must teach or suggest the desirability of the claimed subject matter. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). See also MPEP § 2143 - § 2143.03.

Smith et al. does not motivate derivation of amended claim 22, because Smith et al. does not motivate derivation of a device comprising a movable support member capable of being moved a distance through the cover in a forward direction, and which has a plurality of outer blades extending in the same forward direction, and further extending downward from the support member at an angle in the range from about 50 degrees to about 80 degrees.

For example, the piercing mechanism 24 as taught by Smith et al., comprises a penetrating element 140 having crossing internal walls 142 and pointed blade structure 144 which is designed to move downward to directly penetrate the receptacle, and accordingly, this structure does not motivate derivation of the claimed blades, which extend in the forward direction or a movable structure which is capable of being moved a distance through the cover in a forward direction. Nor does Smith et al.

teach the desirability of extending the blades downward from the support member at an angle in the range from about 50 degrees to about 80 degrees.

In another version, Smith et al. teaches a penetrating structure 151 comprising pointed elements which face each other, and as such, this structure also does not motivate derivation of a plurality of outer blades that extend in the same forward direction as that along which a movable support holding the blades can be moved, as claimed in claim 22.

In still another version, Smith et al. teaches a piercing mechanism 24 which is "fixedly mounted" within the base, and accordingly, this version also does not motivate derivation of a movable support member capable of being moved a distance through the cover in a forward direction, as claimed. Further, the sharpened penetrating elements 26, as seen in Fig. 1 of Smith et al. are pointed in a downward direction, and are thus do not motivate derivation of a plurality of outer blades extending in a forward direction, and also extending downward from the support member at an angle in the range from about 50 degrees to about 80 degrees, as claimed in claim 22.

The Fig. 7 version of Smith et al. also does not motivate derivation of the claimed device comprising a plurality of outer blades that extend in the same forward direction as that along which the movable support can be moved. Nor does this structure have blades directed downward from the support member at an angle in the range from about 50 degrees to about 80 degrees, as claimed in claim 22.

Thus since Smith et al. does not teach claim 22 as a whole, or motivate derivation of claim 22, knowledge of the structure must have been derived in hindsight based on Applicant's own disclosure. Furthermore, the device that would result from the combination of Smith et al. with the suggestions made by the Examiner, does not have a reasonable expectation of success without the knowledge derived from Applicant's own invention. One of ordinary skill in the art would have no reason to provide a movable support member capable of being moved a distance through the

cover in a forward direction, or a plurality of blades extending forward, or blades directed downward at a particular angle range, as claimed, and the Smith et al. reference provides no motivation to do so.

For these reasons, claim 22 is not obvious over Smith et al..

Claim 24

Smith et al. does not teach claim 24 because Smith et al. does not teach or suggest an aerosolizing apparatus comprising a hole forming device comprising a movable support member capable of being moved a distance through the cover in a forward direction, the movable member having at least one outer blade extending in the same forward direction, and further extending downward from the support member at an angle in the range from about 50 degrees to about 80 degrees, for the same reasons as those provided above for claim 22.

Claim 29

Smith et al. does not teach claim 29 because Smith et al. at least because does not teach or suggest an aerosolizing system comprising a hole forming device comprising a movable support member capable of being moved a distance through the cover in a forward direction, the movable member having at least one outer blade extending in the same forward direction, and further extending downward from the support member at an angle in the range from about 50 degrees to about 80 degrees, for the same reasons as that provided above for claim 22.

The remaining dependent claims of this rejection are not obvious over Smith et al. for the same reasons as those recited for their respective independent claims 22, 24 or 29.

2. Claims 1-21 were also rejected under 35 USC 103(a) as unpatentable over US patent no. 5,740,794 to Smith et al..

Claim 1

Smith et al. does not teach amended claim 1, because Smith et al. does not teach a method for forming multiple openings in a receptacle, the method comprising: providing a receptacle having a cover with an exterior surface and an interior surface covering a cavity; providing a cutting mechanism having multiple blades; piercing the cover with the blades; and moving the blades in a forward direction and across a distance through the cover to create multiple elongate openings in the cover and thereby provide access into the cavity, with the cut portion being removed onto the exterior surface and away from the cavity as the openings are created.

Smith et al. teaches a piercing mechanism 24 having a "...feed tube assembly 100 which permits direct penetration of a medicament receptacle lid" as shown in Figs. 10 and 11A and described in column 17, lines 3-36. [Emphasis added] In the embodiment shown in Fig. 11A, the element 140 having crossing internal walls 142 and pointed blade structure 144 is directed downward to puncture the cover of the receptacle - and not a distance through the cover in a forward direction. Thus Smith et al. does not teach "moving the blades in a forward direction and across a distance through the cover to create multiple elongate openings in the cover and thereby provide access into the cavity" as claimed in claim 1.

Smith et al. further does not teach the step of removing the cut portion onto the exterior surface and away from the cavity as the openings are created, as claimed in claim 1. Instead, the cut portion of the cover as taught by Smith et al. must be directed into the receptacle because the pointed blade structure 144 punctures the cover with a downward force causing the cut cover portions to be directed away from the curved blade structures and into the receptacle. Thus Smith et al. does not teach removing the cut portion of the cover away from the cavity and onto the exterior surface

to allow the powder within the receptacle to flow more easily out of the cavity and not be blocked by cut portions of the cover that randomly extend into the receptacle.

In the version shown in Fig. 11B, Smith et al. teaches that the penetrating structure 151 comprising pointed elements which are also oriented along the axis of penetration in downward direction so this structure is also directed downward and not in a forward direction a distance through the cover. Further, Smith et al. teaches that "penetrating element 151 is advantageous since it peels back the lid as it is penetrated, leaving the openings 153 clear to receive powder." The penetrating element 151 forces the cut portions of the cover into the receptacle and thus, away from the opening 153. Thus Smith et al. does not teach removing the cut portion of the cover away from the cavity and onto the exterior surface as claimed.

In the version shown in Fig. 7 of Smith et al. which is also cited by the Office Action, Smith et al. also does not teach "moving the blades in a forward direction and across a distance through the cover to create multiple elongate openings in the cover and thereby provide access into the cavity" as claimed in claim 1. The structure also appears to be directed in a downward direction through the cover, and also does not teach removing the cut portion of the cover away from the cavity and onto the exterior surface.

In yet another version which is shown in Fig. 1, Smith et al. teaches a piercing mechanism 24 which is "fixedly mounted" within the base. Column 12, lines 60-67. In this version, the cartridge 22 is reciprocated while the piercing mechanism 24 is held in a fixed position. This action does not meet the claim language "moving the blades in a forward direction and across a distance through the cover to create multiple elongate openings in the cover and thereby provide access into the cavity" as claimed in claim 1. Smith et al. also does not teach removing the cut portion of the cover away from the cavity and onto the exterior surface, as claimed.

Further, Smith et al. when considered as a whole, does not teach or suggest the desirability of the claimed subject matter. Smith et al. does not motivate derivation of amended claim 1, because Smith et al. does not teach or suggest a process step comprising moving one or more blades in a forward direction and across a distance through the cover to create multiple elongate openings in the cover and thereby provide access into the cavity, as claimed in claim 1. For example, the piercing mechanism 24 comprising a penetrating element 140 is taught by Smith et al. to be moved downward to penetrate the receptacle, and accordingly, this structure does not motivate derivation of the claimed process. The penetrating structure 151 comprising pointed elements which face each other is also taught by Smith et al. to be moved downward to penetrate the cover - not in a forward direction along the cover. In still another version, Smith et al. teaches a piercing mechanism 24 which is "fixedly mounted" within the base, and accordingly, this version also does not motivate derivation of a process step comprising moving the blades in a forward direction and across a distance through the cover to create multiple elongate openings, as claimed in claim 1.

Thus Smith et al. does not teach or suggest the process of claim 1 as a whole or motivate derivation of this process. Furthermore, applying the claimed process to the devices taught by Smith et al. would not have a reasonable expectation of success as the devices of Smith et al. are designed to either be fixed in place, or move in a downward direction. For example, there is no reasonable expectation of success that the pointed blade structure 144 shown in Fig. 11A would actually work if the blades are moved in a forward direction across a distance through the cover because the pointed blade structure extends and points downward along the direction of the axis of the support element 140, and the blade sharp edge does not point in a forward direction.

For these reasons, claim 1 is not obvious over Smith et al..

Claim 12

Smith et al. does not teach claim 12 because Smith et al. at least because does not teach or suggest a method for aerosolizing a powder, comprising, inter alia, moving an outer blade in a forward direction and across a distance through the cover to cut a portion of the cover to create an outer elongate opening in the cover, for the same reasons as provided above for claim 1. In addition, Smith et al. does not teach removing a cut portion away from the cavity as the opening is created, as claimed in claim 12, for also the same reasons as that identified above.

Claim 21

Smith et al. does not teach claim 21 because Smith et al. at least because Smith et al. does not teach or suggest a method for forming multiple openings in a receptacle, the method comprising: providing a receptacle having a cover with an exterior surface and an interior surface covering a cavity; providing a cutting mechanism having (i) at least one outer blade, and (ii) a tubular body having a distal end with a plurality of inwardly and outwardly facing blades; piercing the cover with the blades; and rotating the cutting mechanism across a distance through the cover to form multiple openings in the cover.

For example, none of the versions taught by Smith et al. teach the process step of rotating a cutting mechanism across a distance through the cover to form multiple openings in the cover, as claimed in claim 21. Instead, Smith et al. teaches a piercing mechanism 24 having a "...feed tube assembly 100 which permits direct penetration of a medicament receptacle lid" as shown in Figs. 10 and 11A and described in column 17, lines 3-36. [Emphasis added] In the embodiment shown in Fig. 11A, the element 140 is directed downward to puncture the cover of the receptacle - and is not rotated across a distance through the cover as claimed. In the version shown in Fig. 11B, the penetrating structure 151 comprising pointed elements which are oriented along the axis of penetration in downward direction; and again this structure is not rotated across a distance through the cover as claimed. In the version shown in Fig. 7, Smith et al. also does not teach rotating a cutting mechanism across a distance to the

cover. In yet another version shown in Fig. 1, Smith et al. teaches a piercing mechanism 24 which is "fixedly mounted" within the base, and as such is also not rotated a distance of the cover as claimed in claim 21.

Thus, Smith et al. when considered as a whole, does not teach or suggest the subject matter of claim 21 because Smith et al. does not teach or suggest the desirability of rotating a cutting mechanism across a distance through a cover to create multiple openings in the cover, as claimed in claim 21. For example, the piercing mechanism 24 comprising a penetrating element 140 and the penetrating structure 151 are both taught by Smith et al. to be moved downward to directly penetrate the receptacle, and accordingly, these structures do not motivate derivation of the claimed process. The comprising pointed elements which face each other is also taught by Smith et al. to be moved downward to penetrate the cover and not rotated a distance through the cover. In still another version, Smith et al. teaches a piercing mechanism 24 which is "fixedly mounted" within the base, and accordingly, this version also does not motivate derivation of a process step comprising rotating a cutting mechanism across a distance through a cover, as claimed in claim 21.

Thus Smith et al. does not teach or suggest the process of claim 21 as a whole or motivate derivation of this process. For these reasons, claim 21 is not obvious over Smith et al..

The remaining claims in this rejection are dependent upon one of the independent claims 1, 12 or 21, and are not obvious over Smith et al. for the same reasons as those recited for their respective independent claims.

CONCLUSION

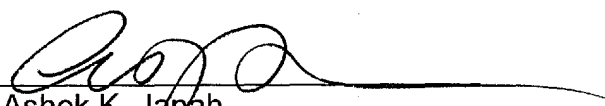
The Examiner is respectfully requested to reconsider the present rejections and allow the pending claims in view of the amendments and remarks made herein. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES, PC

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By: _____


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